

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, and Canadian WHMIS

PART I What is the material and what do I need to know in an emergency?

1. PRODUCT IDENTIFICATION

TRADE NAME/MATERIAL NAME: Imiquimod / Imiquimod Cream 5%

DESCRIPTION:	Imiquimod Cream
NDC #:	0168-0432-24
CHEMICAL NAME (for active ingredient):	1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine
CHEMICAL FAMILY (for active ingredient):	Imidazoquinolines
HOW SUPPLIED:	5% Cream
FORMULA (for active ingredient):	C ₁₄ H ₁₆ N ₄
PRODUCT USE:	Pharmaceutical for Human Use
SUPPLIER/MANUFACTURER'S NAME:	NYCOMED US INC.
ADDRESS:	60 Baylis Road Melville, NY 11747
BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-631-454-7677
EMERGENCY PHONE (U.S./Canada/Puerto Rico):	1-(800) 424-9300
EMERGENCY PHONE (OUTSIDE U.S.):	01-(631) 454-7677

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian WHMIS [Controlled Products Regulations] required information is included in appropriate sections based on the U.S. ANSI Z400.1-2004 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

2. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	% w/w
Imiquimod	99011-02-6	5.0%
Benzyl Alcohol	100-51-6	Proprietary
Cetyl Alcohol	36653-82-4	Proprietary
Glycerin	56-81-5	Proprietary
Methylparaben	99-76-3	Proprietary
Oleic Acid	112-80-1	Proprietary
Polysorbate 60	9005-67-8	Proprietary
Stearyl Alcohol	112-92-5	Proprietary
White Petrolatum	8009-03-8	Proprietary
Xanthan Gum	11138-66-2	Proprietary
Water and other components. Each of the other components is present in less than 1 percent concentration (0.1% concentration for potential carcinogens, reproductive toxins, respiratory tract sensitizers, and mutagens).	The remaining components do not contribute any significant additional hazards. All pertinent information has been provided in this document, per the requirements of the Federal Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, and Canadian Workplace Hazardous Materials Identification System Standards (CPR 4).	Balance

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: Product Description: This product is an off-white odorless cream. **Health Hazards:** The chief health hazard associated with exposure during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing the active ingredient, Imiquimod, or any other components of this product may experience allergic reactions to this product. Repeated ingestion of Imiquimod may cause adverse embryofetal and teratogenic effects, based on animal data. **Flammability Hazards:** If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** This product has not been tested for environmental effects. Large quantities released to the aquatic and terrestrial environment may have an adverse effect. **Emergency Considerations:** Emergency responders should wear appropriate protection for situation to which they respond.

Nycomed US Inc.

PART II *What should I do if a hazardous situation occurs?*

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: If adverse skin effects occur, discontinue use. Seek medical attention.

EYE EXPOSURE: If this product contaminates the eyes, rinse eyes under gently running water. Use sufficient force to open eyelids and then "roll" eyes while flushing. Minimum flushing is for 15 minutes. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If vapors of this product are inhaled, causing irritation, remove victim to fresh air. If necessary, use artificial respiration to support vital functions.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing skin conditions may be aggravated by repeated overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treat symptoms and eliminate exposure.

5. FIRE-FIGHTING MEASURES

FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

Water Spray: OK Carbon Dioxide: OK Foam: OK

Dry Chemical: OK Halon: OK Other: Any "ABC" Class

FIRE EXTINGUISHING MATERIALS NOT TO BE USED: None known.

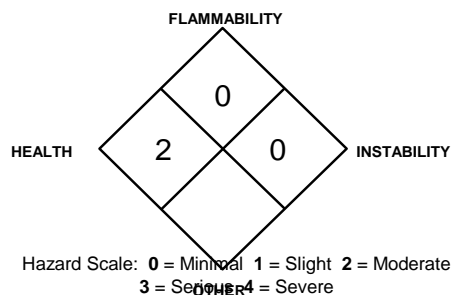
UNUSUAL FIRE AND EXPLOSION HAZARDS: This product contains potential skin and/or skin sensitizers so this product presents a contact hazard to firefighters. If heated to high temperatures for a prolonged period, the water in this product can evaporate off and the residue may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

NFPA RATING



6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: Wipe up spilled product and wipe area with damp sponge or polypad. Place all spill residue in an appropriate container and seal. Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations or waste disposal regulations of Canada (see Section 13, Disposal Considerations).

PART III *How can I prevent hazardous situations from occurring?*

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration.

7. HANDLING and USE (Continued)

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad. Collect all rinsates and dispose of according to applicable U.S. Federal, State, and local hazardous waste disposal regulations or waste disposal regulations of Canada. All disposable items contaminated with this product should be disposed of properly.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR							
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	OTHER
		TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	TWA mg/m ³	STEL mg/m ³	IDLH mg/m ³	
Imiquimod	67915-31-5	NE	NE	NE	NE	NE	NE	NE	NE
Benzyl Alcohol	100-51-6	NE	NE	NE	NE	NE	NE	NE	AIHA WEELS: TWA = 10 ppm
Cetyl Alcohol	36653-82-4	NE	NE	NE	NE	NE	NE	NE	NE
Glycerin	56-81-5	10 (mist)	NE	15 (Total dust) 5 (Resp. fraction) 10 (Total) 5 (Resp. fraction) [vacated 1989 PEL]	NE	NE	NE	NE	DFG MAKs: TWA = 50 (Inhalable fraction) PEAK = 2•MAK 15 min, average value, 1-hr interval DFG MAK Pregnancy Risk Classification: C
Methylparaben	99-76-3	NE	NE	NE	NE	NE	NE	NE	NE
Oleic Acid	112-80-1	NE	NE	NE	NE	NE	NE	NE	NE
Polysorbate 60	9005-67-8	NE	NE	NE	NE	NE	NE	NE	NE
Stearyl Alcohol	112-92-5	NE	NE	NE	NE	NE	NE	NE	NE
White Petrolatum	8009-03-8	NE	NE	NE	NE	NE	NE	NE	NE
Xanthan Gum	11138-66-2	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established.

See Section 16 for Definitions of Other Terms Used

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standards of Canada (including CSA Standard Z94.4-02 and CSA Standard Z94.3-02). Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).

EYE PROTECTION: Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133 or Canadian CSA Standard Z94.3-02.

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff. If necessary, refer to U.S. OSHA 29 CFR 1910.138 or appropriate standards of Canada.

BODY PROTECTION: During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136 or appropriate standards of Canada.

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not established. **FREEZING/MELTING POINT:** Not established.
EVAPORATION RATE (nBuAc = 1): Not established. **SOLUBILITY IN WATER:** Slightly soluble.
VAPOR PRESSURE (air = 1): Not established. **SPECIFIC GRAVITY (water = 1):** Not established.
ODOR THRESHOLD: Not established. **pH:** Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is an off-white cream.
HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product is a distinguishing characteristic to identify the product in event of accidental release.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.
DECOMPOSITION PRODUCTS: *Combustion:* If exposed to extremely high temperatures, thermal decomposition may generate irritating fumes and toxic gases (e.g., carbon oxides and nitrogen oxides). *Hydrolysis:* None known.
MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
HAZARDOUS POLYMERIZATION: Will not occur.
CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE:

The health hazard information provided below is pertinent to medical employees handling this product in an occupational setting. This product is designed for application on the skin. The following paragraphs describe the symptoms of exposure by route of exposure.



INHALATION: Although unlikely due to form of product, inhalation of vapors of this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air. Due to the presence of Methylparaben, this product may cause respiratory sensitization in susceptible individuals; subsequent exposure to very small amounts may cause an asthma-like reaction in sensitive individuals.

CONTACT WITH SKIN or EYES: Skin contact can cause mild moderate irritation, which is alleviated upon rinsing with soap and water. Due the presence of Benzyl Alcohol (a weak skin sensitizer) and Methylparaben, skin contact may cause an allergic reaction in sensitive individuals; subsequent exposure to very small amounts may cause an allergic reaction in sensitive individuals, with symptoms of redness, itching, welts and irritation. Eye contact may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: The Benzyl Alcohol component of this product may be absorbed through the skin. Although skin absorption is not expected to contribute significantly to overall exposure, there is a possibility of low blood pressure from prolonged and repeated skin absorption of this product and symptoms such as those described for "Other Potential Health Effects".

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include nausea, vomiting, diarrhea, fatigue, chills, headache, and low blood pressure.

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "Other Potential Health Effects".

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD	(BLUE)	2*	
FLAMMABILITY HAZARD	(RED)	0	
PHYSICAL HAZARD	(YELLOW)	0	
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications
Hazard Scale: 0 – Minimal 1 – Slight 2 – Moderate
3 = Serious 4 = Severe * = Chronic hazard

11. TOXICOLOGICAL INFORMATION (Continued)

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Persons using the product in therapeutic doses have experienced redness, swelling, skin erosion, flaking skin, induration, ulceration, scabbing, vesicles, soreness, flu-like symptoms, muscle aches, itching, burning, headache, hypo-pigmentation, pain, rash, sensitivity, bleeding, fever, and diarrhea.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin. Accidental ingestion may be harmful. Although unlikely, inhalation can cause irritation of respiratory system. Eye contact will cause irritation.

CHRONIC: Due to the presence of several potential skin and/or respiratory sensitizers, susceptible persons may experience allergic reaction.

TARGET ORGANS:

ACUTE: Occupational Exposure: Skin, eyes. Therapeutic Doses: Skin.

CHRONIC: Occupational Exposure: Skin. Therapeutic Doses: Skin.

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing the Imiquimod component of this product or any other components of this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

For Males and Females: Persons using the product in therapeutic doses may experience redness, swelling, skin erosion, flaking skin, induration, ulceration, scabbing, vesicles, soreness, flu-like symptoms, muscle aches, itching, burning, headache, hypopigmentation, pain, rash, sensitivity, bleeding, fever, and diarrhea.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION OF PRODUCT: The Benzyl Alcohol component of this product is a weak skin sensitizer; skin contact may cause an allergic reaction in sensitive individuals. The Methylparaben component of this product may cause respiratory and skin sensitization; subsequent exposure to very small amounts may cause an allergic reaction in sensitive individuals.

TOXICITY DATA: Currently, there are no toxicity data available for the active component of this product, Imiquimod. Additional data are available for the excipient components of this product, but are not presented in this MSDS; Contact Nycomed US Inc. for more information.

CARCINOGENIC INFORMATION: The following information is available from carcinogenic studies performed with the active ingredient of this product, Imiquimod and studies involving the product:

In an oral (gavage) rat carcinogenicity study, Imiquimod was administered to Wistar rats on a 2X/week (up to 6 mg/kg/day) or daily (3 mg/kg/day) dosing schedule for 24 months. No treatment related tumors were noted in the oral rat carcinogenicity study up to the highest doses tested in this study of 6 mg/kg administered 2X/week in female rats (87X MRHD based on weekly AUC comparisons), 4 mg/kg administered 2X/week in male rats (75X MRHD based on weekly AUC comparisons) or 3 mg/kg administered 7X/week to male and female rats (153X MRHD based on weekly AUC comparisons).

In a dermal mouse carcinogenicity study, Imiquimod cream (up to 5 mg/kg/application Imiquimod or 0.3% Imiquimod cream) was applied to the backs of mice 3X/week for 24 months. A statistically significant increase in the incidence of liver adenomas and carcinomas was noted in high dose male mice compared to control male mice (251X MRHD based on weekly AUC comparisons). An increased number of skin papillomas was observed in vehicle cream control group animals at the treated site only.

In a 52-week dermal photoco-carcinogenicity study, the median time to onset of skin tumor formation was decreased in hairless mice following chronic topical dosing (3X/week; 40 weeks of treatment followed by 12 weeks of observation) with concurrent exposure to UV radiation (5 days per week) with the Cream vehicle alone. No additional effect on tumor development beyond the vehicle effect was noted with the addition of the active ingredient, Imiquimod, to the vehicle cream.

The incipient components of this product are listed by agencies tracking the carcinogenic potential of chemical compounds, as follows:

OLEIC ACID: (MAK-3A) (Substances that cause concern that they could be carcinogens).

The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: The active component of this product, Imiquimod is rated as Pregnancy Category B (NO EVIDENCE OF RISK, Human evidence is negative, but animal evidence is positive. Alternately, there is no human evidence and animal evidence is negative.). Listed below is information concerning the effects of this compound on animal or human reproductive systems.

Mutagenicity: Imiquimod revealed no evidence of mutagenic or clastogenic potential based on the results of five *in vitro* genotoxicity tests (Ames assay, mouse lymphoma L5178Y assay, Chinese hamster ovary cell chromosome aberration assay, human lymphocyte chromosome aberration assay and SHE cell transformation assay) and three *in vivo* genotoxicity tests (rat and hamster bone marrow cytogenetics assay and a mouse dominant lethal test).

11. TOXICOLOGICAL INFORMATION (Continued)

REPRODUCTIVE TOXICITY INFORMATION (continued):

Embryotoxicity: Intravenous doses of 0.5, 1 and 2 mg/kg/day Imiquimod were administered during the period of organogenesis (gestational days 6–18) to pregnant female rabbits. No treatment related effects on embryofetal toxicity were noted at 2 mg/kg/day (1.5X MRHD based on AUC comparisons), the highest dose evaluated in this study, or 1 mg/kg/day (407X MRHD based on AUC comparisons). Oral doses of 1, 5 and 20 mg/kg/day Imiquimod were administered during the period of organogenesis (gestational days 6–15) to pregnant female rats. In the presence of maternal toxicity, fetal effects noted at 20 mg/kg/day [8X MRHD based on body surface area (BSA) comparisons] included increased resorptions. No treatment related effects on embryofetal toxicity were noted at 5 mg/kg/day (55X MRHD based on AUC comparisons).

Teratogenicity: Oral doses of 1, 5 and 20 mg/kg/day Imiquimod were administered during the period of organogenesis (gestational days 6–15) to pregnant female rats. In the presence of maternal toxicity, fetal effects noted at 20 mg/kg/day [8X MRHD based on body surface area (BSA) comparisons] included decreased fetal body weights, delays in skeletal ossification, bent limb bones, and two fetuses in one litter (2 of 1567 fetuses) demonstrated exencephaly, protruding tongues and low-set ears. No treatment related effects on teratogenicity were noted at 5 mg/kg/day (55X MRHD based on AUC comparisons).

Oral doses of 1, 1.5, 3 and 6 mg/kg/day Imiquimod were administered to male rats from 70 days prior to mating through the mating period and to female rats from 14 days prior to mating through parturition and lactation. No effects on growth or post-natal development were noted at doses up to 6 mg/kg/day (87X MRHD based on AUC comparisons), the highest dose evaluated in this study. In the absence of maternal toxicity, bent limb bones were noted in the F1 fetuses at a dose of 6 mg/kg/day (87X MRHD based on AUC comparisons). No treatment related effects on teratogenicity were noted at 3 mg/kg/day (41X MRHD based on AUC comparisons).

Intravenous doses of 0.5, 1 and 2 mg/kg/day Imiquimod were administered during the period of organogenesis (gestational days 6–18) to pregnant female rabbits. No treatment related effects on embryofetal toxicity or teratogenicity were noted at 2 mg/kg/day (1.5X MRHD based on AUC comparisons), the highest dose evaluated in this study, or 1 mg/kg/day (407X MRHD based on AUC comparisons).

Reproductive Toxicity: Daily oral administration of Imiquimod to rats, throughout mating, gestation, parturition and lactation, demonstrated no effects on growth, fertility or reproduction, at doses up to 87X MRHD based on AUC comparisons.

Oral doses of 1, 1.5, 3 and 6 mg/kg/day Imiquimod were administered to male rats from 70 days prior to mating through the mating period and to female rats from 14 days prior to mating through parturition and lactation. No effects on fertility or reproduction were noted at doses up to 6 mg/kg/day (87X MRHD based on AUC comparisons), the highest dose evaluated in this study.

A **mutagen** is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An **embryo toxin** is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A **teratogen** is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A **reproductive toxin** is any substance that interferes in any way with the reproductive process.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: The components of this product will slowly degrade in the environment and form a variety of organic materials.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Handle as if capable of transmitting infectious agents. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION SHIPPING REGULATIONS: This product is NOT classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is NOT classified as Dangerous Goods, per regulations of Transport Canada.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated by the Food and Drug Administration; it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The components of this product are not on the California Proposition 65 lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): CAUTION! MAY CAUSE ALLERGIC REACTION. MAY CAUSE SKIN AND EYE IRRITATION. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. **FIRST-AID:** In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting—seek immediate medical attention. **IN CASE OF FIRE:** Use water fog, dry chemical, CO₂, or “alcohol” foam. **IN CASE OF SPILL:** Wipe up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it exempt from requirements of the DSL/NDL Inventory.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION AND SYMBOLS: Class D2B (Materials Causing Other Toxic Effects—Sensitization)



16. OTHER INFORMATION

This Material Safety Data Sheet is offered pursuant to OSHA's Hazard Communication Standard, 29 CFR, 1910.1200. Other government regulations must be reviewed for applicability to this product. To the best of Nycomed US, Inc.'s knowledge, the information contained herein is reliable and accurate as of this date; however, accuracy, suitability or completeness are not guaranteed and no warranties of any type, either express or implied, are provided. The information contained herein relates only to this specific product. If this product is combined with other materials, all component properties must be considered. Data may be changed from time to time. Be sure to consult the latest edition.

PREPARED BY: CHEMICAL SAFETY ASSOCIATES, Inc.
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REVISION HISTORY: Up-date to current format.

DEFINITION OF TERMS

A large number of abbreviations and acronyms appear on a MSDS. Some of these, which are commonly used, include the following:

CAS #: This is the Chemical Abstract Service Number that uniquely identifies each constituent.

EXPOSURE LIMITS IN AIR:

CEILING LEVEL: The concentration that shall not be exceeded during any part of the working exposure.

DFG MAK Germ Cell Mutagen Categories: 1: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed humans. 2: Germ cell mutagens which have been shown to increase the mutant frequency in the progeny of exposed mammals. 3A: Substances which have been shown to induce genetic damage in germ cells of human of animals, or which produce mutagenic effects in somatic cells of mammals *in vivo* and have been shown to reach the germ cells in an active form.

EXPOSURE LIMITS IN AIR (continued):

DFG MAK Germ Cell Mutagen Categories (continued): 3B: Substances which are suspected of being germ cell mutagens because of their genotoxic effects in mammalian somatic cell *in vivo*; in exceptional cases, substances for which there are no *in vivo* data, but which are clearly mutagenic *in vitro* and structurally related to known *in vivo* mutagens.

4: Not applicable (Category 4 carcinogenic substances are those with non-genotoxic mechanisms of action. By definition, germ cell mutagens are genotoxic. Therefore, a Category 4 for germ cell mutagens cannot apply. At some time in the future, it is conceivable that a Category 4 could be established for genotoxic substances with primary targets other than DNA [e.g. purely aneugenic substances] if research results make this seem sensible.)

DEFINITION OF TERMS (Continued)

EXPOSURE LIMITS IN AIR (continued):

DFG MAK Germ Cell Mutagen Categories (continued): 5: Germ cell mutagens, the potency of which is considered to be so low that, provided the MAK value is observed, their contribution to genetic risk for humans is expected not to be significant.

DFG MAK Pregnancy Risk Group Classification: Group A: A risk of damage to the developing embryo or fetus has been unequivocally demonstrated. Exposure of pregnant women can cause damage of the developing organism, even when MAK and BAT (Biological Tolerance Value for Working Materials) values are observed. **Group B:** Currently available information indicates a risk of damage to the developing embryo or fetus must be considered to be probable. Damage to the developing organism cannot be excluded when pregnant women are exposed, even when MAK and BAT values are observed. **Group C:** There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are observed. **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend, **Group D:** Classification in one of the groups A-C is not yet possible because, although the data available may indicate a trend.

IDLH-Immediately Dangerous to Life and Health: This level represents a concentration from which one can escape within 30-minutes without suffering escape-preventing or permanent injury.

LOQ: Limit of Quantitation.

MAK: Federal Republic of Germany Maximum Concentration Values in the workplace.

NE: Not Established. When no exposure guidelines are established, an entry of NE is made for reference.

NIC: Notice of Intended Change.

NIOSH CEILING: The exposure that shall not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling shall be assumed as a 15-minute TWA exposure (unless otherwise specified) that shall not be exceeded at any time during a workday.

NIOSH RELS: NIOSH's Recommended Exposure Limits.

PEL-Permissible Exposure Limit: OSHA's Permissible Exposure Limits. This exposure value means exactly the same as a TLV, except that it is enforceable by OSHA. The OSHA Permissible Exposure Limits are based in the 1989 PELs and the June, 1993 Air Contaminants Rule (Federal Register, 58: 35338-35351 and 58: 40191). Both the current PELs and the vacated PELs are indicated. The phrase, "Vacated 1989 PEL," is placed next to the PEL that was vacated by Court Order.

SKIN: Used when there is a danger of cutaneous absorption.

STEL-Short Term Exposure Limit: Short Term Exposure Limit, usually a 15-minute time-weighted average (TWA) exposure that should not be exceeded at any time during a workday, even if the 8-hr TWA is within the TLV-TWA, PEL-TWA or REL-TWA.

TLV-Threshold Limit Value: An airborne concentration of a substance that represents conditions under which it is generally believed that nearly all workers may be repeatedly exposed without adverse effect. The duration must be considered, including the 8-hour.

TWA-Time Weighted Average: Time Weighted Average exposure concentration for a conventional 8-hr (TLV, PEL) or up to a 10-hr (REL) workday and a 40-hr workweek.

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM

HAZARD RATINGS: This rating system was developed by the National Paint and Coating Association and has been adopted by industry to identify the degree of chemical hazards.

HEALTH HAZARD: 0 (Minimal Hazard): No significant health risk, irritation of skin or eyes not anticipated. *Skin Irritation:* Essentially non-irritating. PII or Draize = "0". *Eye Irritation:* Essentially non-irritating, or minimal effects which clear in < 24 hours [e.g. mechanical irritation]. Draize = "0". *Oral Toxicity LD₅₀ Rat < 5000 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: < 2000 mg/kg. Inhalation Toxicity 4-hrs LC₅₀ Rat: < 20 mg/L; 1 (Slight Hazard):* Minor reversible injury may occur; slightly or mildly irritating. *Skin Irritation:* Slightly or mildly irritating. *Eye Irritation:* Slightly or mildly irritating. *Oral Toxicity LD₅₀ Rat: > 500-5000 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: > 1000-2000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat > 2-20 mg/L; 2 (Moderate Hazard):* Temporary or transitory injury may occur. *Skin Irritation:* Moderately irritating; primary irritant; sensitizer. PII or Draize > 0, < 5. *Eye Irritation:* Moderately to severely irritating and/or corrosive; reversible corneal opacity; corneal involvement or irritation clearing in 8-21 days. Draize > 0, ≤ 25. *Oral Toxicity LD₅₀ Rat: > 50-500 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: > 200-1000 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 0.5-2 mg/L; 3 (Serious Hazard):* Major injury likely unless prompt action is taken and medical treatment is given; high level of toxicity; corrosive. *Skin Irritation:* Severely irritating and/or corrosive; may destroy dermal tissue, cause skin burns, dermal necrosis. PII or Draize > 5-8 with destruction of tissue. *Eye Irritation:* Corrosive, irreversible destruction of ocular tissue; corneal involvement or irritation persisting for more than 21 days. Draize > 80 with effects irreversible in 21 days. *Oral Toxicity LD₅₀ Rat: > 1-50 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: > 20-200 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: > 0.05-0.5 mg/L; 4 (Severe Hazard):* Life-threatening; major or permanent damage may result from single or repeated exposure. *Skin Irritation:* Not appropriate. Do not rate as a "4", based on skin irritation alone. *Eye Irritation:* Not appropriate. Do not rate as a "4", based on eye irritation alone. *Oral Toxicity LD₅₀ Rat: ≤ 1 mg/kg. Dermal Toxicity LD₅₀Rat or Rabbit: ≤ 20 mg/kg. Inhalation Toxicity LC₅₀ 4-hrs Rat: ≤ 0.05 mg/L.*

FLAMMABILITY HAZARD: 0 (Minimal Hazard-Materials) that will not burn in air when exposure to a temperature of 815.5°C [1500°F] for a period of 5 minutes.);

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM

HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 1 (Slight Hazard-Materials) that must be pre-heated before ignition can occur. Material require considerable pre-heating, under all ambient temperature conditions before ignition and combustion can occur. Including: Materials that will burn in air when exposed to a temperature of 815.5°C (1500°F) for a period of 5 minutes or less; Liquids, solids and semisolids having a flash point at or above 93.3°C [200°F] (e.g. OSHA Class IIIB, or; Most ordinary combustible materials [e.g. wood, paper, etc.]; **2 (Moderate Hazard-Materials)** that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not, under normal conditions, form hazardous atmospheres in air, but under high ambient temperatures or moderate heating may release vapor in sufficient quantities to produce hazardous atmospheres in air. Including: Liquids having a flash-point at or above 37.8°C [100°F]; Solid materials in the form of coarse dusts that may burn rapidly but that generally do not form explosive atmospheres; Solid materials in a fibrous or shredded form that may burn rapidly and create flash fire hazards (e.g. cotton, sisal, hemp; Solids and semisolids that readily give off flammable vapors.); **3 (Serious Hazard- Liquids and solids)** that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures, or, unaffected by ambient temperature, are readily ignited under almost all conditions, including: Liquids having a flash point below 22.8°C [73°F] and having a boiling point at or above 38°C [100°F] and below 37.8°C [100°F] [e.g. OSHA Class IB and IC]; Materials that on account of their physical form or environmental conditions can form explosive mixtures with air and are readily dispersed in air [e.g., dusts of combustible solids, mists or droplets of flammable liquids]; Materials that burn extremely rapidly, usually by reason of self-contained oxygen [e.g. dry nitrocellulose and many organic peroxides]; **4 (Severe Hazard-Materials)** that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air, and which will burn readily, including: Flammable gases; Flammable cryogenic materials; Any liquid or gaseous material that is liquid while under pressure and has a flash point below 22.8°C [73°F] and a boiling point below 37.8°C [100°F] [e.g. OSHA Class IA; Material that ignite spontaneously when exposed to air at a temperature of 54.4°C [130°F] or below [e.g. pyrophoric].

PHYSICAL HAZARD: 0 (Water Reactivity): Materials that do not react with water. *Organic Peroxides:* Materials that are normally stable, even under fire conditions and will not react with water. *Explosives:* Substances that are Non-Explosive. *Unstable Compressed Gases:* No Rating. *Pyrophorics:* No Rating. *Oxidizers:* No "0" rating allowed. *Unstable Reactives:* Substances that will not polymerize, decompose, condense or self-react.; **1 (Water Reactivity):** Materials that change or decompose upon exposure to moisture. *Organic Peroxides:* Materials that are normally stable, but can become unstable at high temperatures and pressures. These materials may react with water, but will not release energy. *Explosives:* Division 1.5 & 1.6 substances that are very insensitive explosives or that do not have a mass explosion hazard. *Compressed Gases:* Pressure below OSHA definition. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group III; *Solids:* any material that in either concentration tested, exhibits a mean burning time less than or equal to the mean burning time of a 3:7 potassium bromate/cellulose mixture and the criteria for Packing Group I and II are not met. *Liquids:* any material that exhibits a mean pressure rise time less than or equal to the pressure rise time of a 1:1 nitric acid (65%)/cellulose mixture and the criteria for Packing Group I and II are not met. *Unstable Reactives:* Substances that may decompose, condense or self-react, but only under conditions of high temperature and/or pressure and have little or no potential to cause significant heat generation or explosive hazard. Substances that readily undergo hazardous polymerization in the absence of inhibitors.); **2 (Water Reactivity):** Materials that may react violently with water. *Organic Peroxides:* Materials that, in themselves, are normally unstable and will readily undergo violent chemical change, but will not detonate. These materials may also react violently with water. *Explosives:* Division 1.4 – Explosive substances where the explosive effect are largely confined to the package and no projection of fragments of appreciable size or range are expected. An external fire must not cause virtually instantaneous explosion of almost the entire contents of the package. *Compressed Gases:* Pressurized and meet OSHA definition but < 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group II *Solids:* any material that, either in concentration tested, exhibits a mean burning time of less than or equal to the mean burning time of a 2:3 potassium bromate/cellulose mixture and the criteria for Packing Group I are not met. *Liquids:* any material that exhibits a mean pressure rise time less than or equal to the pressure rise of a 1:1 aqueous sodium chlorate solution (40%)/cellulose mixture and the criteria for Packing Group I are not met. *Reactives:* Substances that may polymerize, decompose, condense, or self-react at ambient temperature and/or pressure, but have a low potential for significant heat generation or explosion. Substances that readily form peroxides upon exposure to air or oxygen at room temperature); **3 (Water Reactivity):** Materials that may form explosive reactions with water. *Organic Peroxides:* Materials that are capable of detonation or explosive reaction, but require a strong initiating source, or must be heated under confinement before initiation; or materials that react explosively with water. *Explosives:* Division 1.2 – Explosive substances that have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but do not have a mass explosion hazard. *Compressed Gases:* Pressure ≥ 514.7 psi absolute at 21.1°C (70°F) [500 psig]. *Pyrophorics:* No Rating. *Oxidizers:* Packaging Group I *Solids:* any material that, in either concentration tested, exhibits a mean burning time less than the mean burning time of a 3:2 potassium bromate/cellulose mixture.

DEFINITION OF TERMS (Continued)

HAZARDOUS MATERIALS IDENTIFICATION SYSTEM HAZARD RATINGS (continued):

PHYSICAL HAZARD (continued): 3 (continued): Liquids: Any material that spontaneously ignites when mixed with cellulose in a 1:1 ratio, or which exhibits a mean pressure rise time less than the pressure rise time of a 1:1 perchloric acid (50%)/cellulose mixture. *Unstable Reactives:* Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a moderate potential to cause significant heat generation or explosion.; . **4 (Water Reactivity):** Materials that react explosively with water without requiring heat or confinement. *Organic Peroxides:* Materials that are readily capable of detonation or explosive decomposition at normal temperature and pressures. *Explosives:* Division 1.1 & 1.2-explosive substances that have a mass explosion hazard or have a projection hazard. A mass explosion is one that affects almost the entire load instantaneously. *Compressed Gases:* No Rating. *Pyrophorics:* Add to the definition of Flammability "4". *Oxidizers:* No "4" rating. *Unstable Reactives:* Substances that may polymerize, decompose, condense or self-react at ambient temperature and/or pressure and have a high potential to cause significant heat generation or explosion.)

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS:

HEALTH HAZARD: 0 (materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 10,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 200 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 2000 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 2000 mg/kg. Materials that are essentially non-irritating to the respiratory tract, eyes and skin. **1** (materials that, under emergency conditions, can cause significant irritation): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 5,000 ppm but less than or equal to 10,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 10 mg/L but less than or equal to 200 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 1000 mg/kg but less than or equal to 2000 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 500 mg/kg but less than or equal to 2000 mg/kg. Materials that cause slight to moderate irritation to the respiratory tract, eyes and skin. **2** (materials that, under emergency conditions, can cause temporary incapacitation or residual injury): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 3,000 ppm but less than or equal to 5,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 2 mg/L but less than or equal to 10 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 200 mg/kg but less than or equal to 1000 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 50 mg/kg but less than or equal to 500 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 5000 ppm and that does not meet the criteria for either degree of hazard 3 or degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause severe tissue damage, depending on duration of exposure. Materials that are respiratory irritants. Materials that cause severe, but reversible irritation to the eyes or are lachrymators. Materials that are primary skin irritants or sensitizers. **3** (materials that, under emergency conditions, can cause serious or permanent injury): Gases and vapors whose LC₅₀ for acute inhalation toxicity is greater than 1,000 ppm but less than or equal to 3,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is greater than 0.5 mg/L but less than or equal to 2 mg/L. Materials whose LD₅₀ for acute dermal toxicity is greater than 40 mg/kg but less than or equal to 200 mg/kg. Materials whose LD₅₀ for acute oral toxicity is greater than 5 mg/kg but less than or equal to 50 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 3000 ppm and that does not meet the criteria for degree of hazard 4. Compressed liquefied gases with boiling points between -30°C (-22°F) and -55°C (-66.5°F) that cause frostbite and irreversible tissue damage. Materials that are respiratory irritants. Cryogenic gases that cause frostbite and irreversible tissue damage. Materials that are corrosive to the respiratory tract. Materials that are corrosive to the eyes or cause irreversible corneal opacity. Materials that are corrosive to the skin. **4** (materials that, under emergency conditions, can be lethal): Gases and vapors whose LC₅₀ for acute inhalation toxicity less than or equal to 1,000 ppm. Dusts and mists whose LC₅₀ for acute inhalation toxicity is less than or equal to 0.5 mg/L. Materials whose LD₅₀ for acute dermal toxicity is less than or equal to 40 mg/kg. Materials whose LD₅₀ for acute oral toxicity is less than or equal to 5 mg/kg. Any liquid whose saturated vapor concentration at 20°C (68°F) is equal to or greater than one-fifth its LC₅₀ for acute inhalation toxicity, if its LC₅₀ is less than or equal to 1000 ppm.

FLAMMABILITY HAZARD: 0 Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as concrete, stone, and sand: Materials that will not burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. **1** Materials that must be preheated before ignition can occur. Materials in this degree require considerable preheating, under all ambient temperature conditions, before ignition and combustion can occur: Materials that will burn in air when exposed to a temperature of 816°C (1500°F) for a period of 5 minutes in accordance with Annex D. Liquids, solids and semisolids having a flash point at or above 93.4°C (200°F) (i.e. Class IIIB liquids). Liquids with a flash point greater than 35°C (95°F) that do not sustain combustion when tested using the *Method of Testing for Sustained Combustibility*, per 49 CFR 173, Appendix H or the UN *Recommendation on the Transport of Dangerous Goods, Model Regulations* (current edition) and the related *Manual of Tests and Criteria* (current edition).

NATIONAL FIRE PROTECTION ASSOCIATION HAZARD RATINGS (continued):

FLAMMABILITY HAZARD (continued): 1 (continued): Liquids with a flash point greater than 35°C (95°F) in a water-miscible solution or dispersion with a water non-combustible liquid/solid content of more than 85 percent by weight. Liquids that have no fire point when tested by ASTM D 92 Standard Test Method for Flash and Fire Points by Cleveland Open Cup, up to a boiling point of the liquid or up to a temperature at which the sample being tested shows an obvious physical change. Combustible pellets with a representative diameter of greater than 2 mm (10 mesh). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. Most ordinary combustible materials. **2** Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur. Materials in this degree would not under normal conditions form hazardous atmospheres with air, but under high ambient temperatures or under moderate heating could release vapor in sufficient quantities to produce hazardous atmospheres with air: Liquids having a flash point at or above 37.8°C (100°F) and below 93.4°C (200°F) (i.e. Class II and Class IIIA liquids.) Solid materials in the form of powders or coarse dusts of representative diameter between 420 microns (40 mesh) and 2 mm (10 mesh) that burn rapidly but that generally do not form explosive mixtures in air. Solid materials in fibrous or shredded form that burn rapidly and create flash fire hazards, such as cotton, sisal and hemp. Solids and semisolids that readily give off flammable vapors. Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. **3** Liquids and solids that can be ignited under almost all ambient temperature conditions. Materials in this degree produce hazardous atmospheres with air under almost all ambient temperatures or, though unaffected by ambient temperatures, are readily ignited under almost all conditions: Liquids having a flash point below 22.8°C (73°F) and having a boiling point at or above 37.8°C (100°F) and those liquids having a flash point at or above 22.8°C (73°F) and below 37.8°C (73°F) and below 37.8°C (100°F) (i.e. Class IB and IC liquids). Materials that, on account of their physical form or environmental conditions, can form explosive mixtures with air and are readily dispersed in air. Flammable or combustible dusts with a representative diameter less than 420 microns (40 mesh). Materials that burn with extreme rapidity, usually by reason of self-contained oxygen (e.g. dry nitrocellulose and many organic peroxides). Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent. **4** Materials that will rapidly or completely vaporize at atmospheric pressure and normal ambient temperature or that are readily dispersed in air and will burn readily: Flammable gases. Flammable cryogenic materials. Any liquid or gaseous materials that is liquid while under pressure and has a flash point below 22.8°C (73°F) and a boiling point below 37.8°C (100°F) (i.e. Class IA liquids). Materials that ignite when exposed to air, Solids containing greater than 0.5 percent by weight of a flammable or combustible solvent are rated by the closed up flash point of the solvent.

INSTABILITY HAZARD: 0 Materials that in themselves are normally stable, even under fire conditions: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) below 0.01 W/mL. Materials that do not exhibit an exotherm at temperatures less than or equal to 500°C (932°F) when tested by differential scanning calorimetry. **1** Materials that in themselves are normally stable, but that can become unstable at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 0.01 W/mL and below 10 W/mL. **2** Materials that readily undergo violent chemical change at elevated temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 10 W/mL and below 100W/mL. **3** Materials that in themselves are capable of detonation or explosive decomposition or explosive reaction, but that require a strong initiating source or that must be heated under confinement before initiation: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) at or above 100 W/mL and below 1000 W/mL. Materials that are sensitive to thermal or mechanical shock at elevated temperatures and pressures. **4** Materials that in themselves are readily capable of detonation or explosive decomposition or explosive reaction at normal temperatures and pressures: Materials that have an estimated instantaneous power density (product of heat of reaction and reaction rate) at 250°C (482°F) of 1000 W/mL or greater. Materials that are sensitive to localized thermal or mechanical shock at normal temperatures and pressures.

FLAMMABILITY LIMITS IN AIR:

Much of the information related to fire and explosion is derived from the National Fire Protection Association (NFPA). **Flash Point** - Minimum temperature at which a liquid gives off sufficient vapors to form an ignitable mixture with air. **Autoignition Temperature:** The minimum temperature required to initiate combustion in air with no other source of ignition. **LEL** - the lowest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source. **UEL** - the highest percent of vapor in air, by volume, that will explode or ignite in the presence of an ignition source.

DEFINITION OF TERMS (Continued)

TOXICOLOGICAL INFORMATION:

Human and Animal Toxicology: Possible health hazards as derived from human data, animal studies, or from the results of studies with similar compounds are presented. Definitions of some terms used in this section are: **LD₅₀** - Lethal Dose (solids & liquids) which kills 50% of the exposed animals; **LC₅₀** - Lethal Concentration (gases) which kills 50% of the exposed animals; **ppm** concentration expressed in parts of material per million parts of air or water; **mg/m³** concentration expressed in weight of substance per volume of air; **mg/kg** quantity of material, by weight, administered to a test subject, based on their body weight in kg. Other measures of toxicity include **TDLo**, the lowest dose to cause a symptom and **TCLo** the lowest concentration to cause a symptom; **TDo**, **LDLo**, and **LDo**, or **TC**, **TCo**, **LCLo**, and **LCo**, the lowest dose (or concentration) to cause lethal or toxic effects. **Cancer Information:** The sources are: **IARC** - the International Agency for Research on Cancer; **NTP** - the National Toxicology Program, **RTECS** - the Registry of Toxic Effects of Chemical Substances, **OSHA** and **CAL/OSHA**. IARC and NTP rate chemicals on a scale of decreasing potential to cause human cancer with rankings from 1 to 4. Subrankings (2A, 2B, etc.) are also used. **Other Information:** **BEI** - ACGIH Biological Exposure Indices, represent the levels of determinants which are most likely to be observed in specimens collected from a healthy worker who has been exposed to chemicals to the same extent as a worker with inhalation exposure to the TLV.

ECOLOGICAL INFORMATION:

EC is the effect concentration in water. **BCF** = Bioconcentration Factor, which is used to determine if a substance will concentrate in lifeforms which consume contaminated plant or animal matter. **TL_m** = median threshold limit; Coefficient of Oil/Water Distribution is represented by **log K_{ow}** or **log K_{oc}** and is used to assess a substance's behavior in the environment.

REGULATORY INFORMATION:

U.S. and CANADA:

This section explains the impact of various laws and regulations on the material. **EPA** is the U.S. Environmental Protection Agency. **ACGIH:** American Conference of Governmental Industrial Hygienists, a professional association which establishes exposure limits. **NIOSH** is the National Institute of Occupational Safety and Health, which is the research arm of the U.S. Occupational Safety and Health Administration (**OSHA**). **WHMIS** is the Canadian Workplace Hazardous Materials Information System. **DOT** and **TC** are the U.S. Department of Transportation and the Transport Canada, respectively. Superfund Amendments and Reauthorization Act (**SARA**); the Canadian Domestic/Non-Domestic Substances List (**DSL/NDL**); the U.S. Toxic Substance Control Act (**TSCA**); Marine Pollutant status according to the **DOT**; the Comprehensive Environmental Response, Compensation, and Liability Act (**CERCLA or Superfund**); and various state regulations. This section also includes information on the precautionary warnings which appear on the material's package label. **OSHA** - U.S. Occupational Safety and Health Administration.